

### **REMARKS**

Reconsideration of the rejections based upon the foregoing amendments and the following remarks is respectfully requested.

- A. Claims 1-5 and 16 were rejected under 35 U.S.C. §103(a) as being unpatentable over Neel et al. (US 6,743,635 B2) in view of Beaty et al. (US 6,645,368 B1) (“Beaty”). Claim 6 was rejected under 35 U.S.C. §103(a) as being unpatentable over Neel in view of Beaty, and further in view of Feldman et al. (US 6,592,745 B1) (“Feldman”). Claims 7-15 were rejected under 35 U.S.C. §103(a) as being unpatentable over Neel in view of Feldman.**

Claim 1 specifically requires “applying a first test signal to at least one of the first pair of electrodes; measuring a first response to the first test signal; maintaining the first pair of electrodes in an inoperative state after the measuring the first response; applying a second test signal to at least one of the second pair of electrodes, wherein the second test signal is a signal having an AC component; measuring a second response to the second test signal; and performing a measurement upon the biological fluid after the measuring the second response.” It is respectfully submitted that the above-recited combination of steps is not taught or suggested in the prior art of record.

The Office Action concedes that Neel teaches the use of a DC signal applied to dose sufficiency electrodes, but does not disclose the use of a signal having an AC component. In an attempt to cure this deficiency, the Office Action suggests that Beaty discloses applying an AC signal to measurement electrodes to determine sample volume sufficiency, therefore it would have been obvious to use a signal having an AC component with the dose sufficiency electrodes of Neel.

It is respectfully submitted that, rather than rendering the claimed invention obvious, the combination of Neel and Beaty teach away from the present invention. Neel teaches the use of a separate pair of dose sufficiency electrodes and the application of a DC signal thereto. The reason that Neel uses a separate pair of dose sufficiency electrodes (i.e. separate from the measurement electrodes) is that Neel teaches that applying a DC signal to the measurement electrodes for purposes of determining dose sufficiency will thereby disturb the reaction between the sample and the reagent in the critical region of the sample chamber for measurement. By applying the DC signal to the dose sufficiency electrodes separate and distinct from the measurement electrodes, and leaving an open circuit between the measurement electrodes, the stoichiometry of the measurement region is not disturbed until the measurement sequence is ready to begin. See Neel, col. 14, line 55 to col. 15, line 25.

The Final Office Action alleges that the above-referenced section of Neel “does not make any mention of how a DC signal applied to the dose sufficiency electrodes [sic; measurement electrodes] may disturb the reaction between the sample and the reagent” (OA, p. 3, ll. 5-6). It is respectfully submitted that, while this is not explicitly detailed in Neel, one of ordinary skill in the art would immediately recognize why Neel turns off the DC voltage applied to the measurement electrodes as soon as sample is detected at the measurement electrodes, and then applies a DC voltage to the separate dose sufficiency electrodes: it is to avoid disturbing the stoichiometry of the reaction between the sample and the reagent. It is well known in the art that a DC bias voltage on the sample/reagent is to be avoided until it is desired to begin the analyte measurement test to determine the Cottrell decay curve.

For example, U.S. Patent No. 6,193,873 discusses in the Background section that

For accurate results, the sample detection procedure should not perturb the analyte concentration, and several techniques for minimizing analyte perturbation have been described [in the prior art].”

(col. 2, ll. 1-4). The ‘873 patent then cites German Pat. App. 148,387, German Pat. App. 208,230, and U.S. Pat. No. 4,490,945 as each teaching that the analyte sample should not be perturbed while the sample is reacting with the reagent. U.S. Pat. No. 6,743,635 is another example of the widespread practice in the prior art to limit the duration of any applied DC potential to the sample prior to initiation of an amperometric measurement sequence. This concept is thus extremely well known in the art.

Unlike Neel, Beaty teaches that the adequacy of the sample volume can be determined by applying an AC signal of proper level directly to the measurement electrodes, without the need for separate dose sufficiency electrodes. This is because an AC signal at the proper level will not drive the sample redox (reduction-oxidation) reaction in one direction. Therefore, a combination of Neel and Beaty teaches either that: 1) the separate dose sufficiency electrodes of Neel are unnecessary since the application of an AC signal to the measurement electrodes achieves the same result without the need for an additional pair of dose sufficiency electrodes, or 2) the AC signal of Beaty that is applied to the measurement electrodes is unnecessary since Neel provides for dedicated dose sufficiency electrodes and the use of a more easily generated DC signal. There is nothing in the combination that would suggest to one of ordinary skill in the art that a signal having an AC component should be applied to separate dose sufficiency electrodes since Beaty demonstrates that this is unnecessary when using an AC signal. Feldman does not lend any weight or support to the findings of the Office Action because it simply does not relate to the use of a signal having an AC component.

The Final Office Action attempts to rebut this argument by suggesting that Applicants are arguing against the modification of Beaty by Neel, when the Office Action originally suggested that

Neel be modified by Beaty. It is alleged that since the Neel design already includes separate dose sufficiency electrodes, the combination of Beaty does not render them superfluous. It is respectfully submitted that one of ordinary skill in the art, when viewing the teachings of Neel and Beaty, would indeed conclude that the separate dose sufficiency electrodes of Neel were superfluous since the use of a dose sufficiency signal having an AC component allows the use of the measurement electrodes for the dose sufficiency measurement. “Real estate” on a biosensor is a precious commodity. No biosensor designer would commit this precious resource to a pair of dose sufficiency electrodes when the prior art demonstrates that they are not needed. Provision of separate dose sufficiency electrodes also requires biosensor real estate for the contact pads that enable the test meter to connect to them, as well as a more complicated test meter connector requiring two extra contacts. The Final Office Action alleges that since the Neel design already has separate dose sufficiency electrodes, modifying Neel with Beaty would lead one of skill in the art to apply an AC signal to the separate dose sufficiency electrodes of Neel. Quite to the contrary, Applicants argue that one skilled in the art would remove the separate dose sufficiency electrodes from the Neel design as being unnecessary when using the AC dose sufficiency signal of Beaty.

The Final Office Action also alleges that

“Beaty does not exclude applying and [sic] AC signal to separate dose sufficiency electrodes. Indeed, Beaty discloses that a DC offset to the AC signal may be useful. See col. 11:32-57 and col. 12:12-19. In such a situation Applicant would surely acknowledge that separate dose sufficiency electrodes would have been obvious since Applicant asserts, as noted above, that Neel allegedly teaches using separate dose sufficiency electrodes to prevent a DC signal from disturbing the reaction between the sample and reagent.”

(OA, p. 3, l. 21 to p. 4, l. 5). It is respectfully submitted that the referenced sections of Beaty that discuss the use of a DC offset with the AC signal relate to measurement of the concentration of an interferent in the sample, and not for determination of sample volume. Beaty clearly states (col. 11, ll. 44-46) that “an interferent’s concentration may readily be ascertained in the optimum frequency

range and optimum DC offset for isolation of that particular interferent's concentration." In other words, a DC offset is only intended to make the impedance measurement more selective (independent) than would be possible without an offset. There is no teaching in Beaty of using a DC offset during the sample volume determination.

Finally, one aspect of the proposed combination of Neel and Beaty that has not been explained in the Final Office Action is why the combination teaches application of an AC signal to the fill-detect electrodes of Neel. As conceded on the second paragraph of page 4 of the Office Action of 11/1/07, "it is not clearly apparent that removing the sample sufficiency electrodes 28 and 30 of Neel would be redundant as Applicant alleges if the sample sufficiency AC signal of Beaty is just applied to the measurement electrodes 22 and 24 of Neel." If this is indeed the case, then the combination teaches applying a DC signal to the fill-detect electrodes and the combination still does not meet the limitations of Applicants' claim 1. Beaty teaches application of an AC sample sufficiency signal to the measurement electrodes. Neel teaches the use of a DC signal on separate fill-detect electrodes. If the use of the Beaty AC signal on the measurement electrodes of Neel still requires the use of the fill-detect electrodes, as alleged in the Office Action, then the only teaching of the use of the fill-detect electrodes in the combination is the application of a DC signal thereto, which does not meet the limitations of Applicants' claim 1. Nowhere does the combination of Neel and Beaty teach that there is any reason to apply an AC signal to electrodes downstream from the measurement electrodes. Such is only taught in the present application. It is therefore respectfully submitted that Applicants' claim 1 is allowable in view of the references of record.

Claims 2-6 and 16 depend from claim 1 and therefore include all of the limitations of claim 1. It is therefore respectfully submitted that claims 2-6 and 16 are allowable over the references of record for at least the same reasons set forth above with respect to claim 1.

Claim 7, as amended, specifically requires “a third pair of electrodes in operative communication with the chamber” and “third measuring an analyte concentration of the biological fluid using the third pair of electrodes; wherein the first pair of electrodes and the second pair of electrodes are not used to measure the first analyte concentration or any second analyte concentration.” It is respectfully submitted that the Neel et al. reference does not disclose the above-recited element of Applicants’ claim 7. Neel et al. discloses only two pairs of electrodes. The Office Action alleges that this deficiency in Neel et al. is cured by Feldman et al., which discloses three working electrodes. The Office Action specifically states that “[a]lthough Neel discloses that the first pair of electrodes is used for both determining the beginning of the fill-time and for measuring an analyte this does not exclude providing one or more additional pairs of electrodes for measuring other analytes” (Office Action, pp. 7-8). It is respectfully submitted that such a combination would result in one of the fill time detect electrodes still having a dual use as a measurement electrode, in contravention to Applicants’ claim 7, as amended. It is therefore respectfully submitted that Applicants’ claim 7 is allowable over the references of record.

Claims 8-11 depend from claim 7 and therefore include all of the limitations of claim 7. It is therefore respectfully submitted that claims 8-11 are allowable over the references of record for at least the same reasons set forth above with respect to claim 7.

Claim 12, as amended, specifically requires “a third pair of electrodes in operative communication with the chamber” and “determining a concentration of an analyte in the biological fluid using the third response; wherein the first pair of electrodes and the second pair of electrodes are not used to measure the first analyte concentration or any second analyte concentration.” It is respectfully submitted that the Neel et al. reference does not disclose the above-recited element of Applicants’ claim 12. Neel et al. discloses only two pairs of electrodes. The Office Action alleges that this deficiency in Neel et al. is cured by Feldman et al., which discloses three working

electrodes. The Office Action specifically states that “[a]lthough Neel discloses that the first pair of electrodes is used for both determining the beginning of the fill-time and for measuring an analyte this does not exclude providing one or more additional pairs of electrodes for measuring other analytes” (Office Action, pp. 7-8, as referenced on p. 8, ll. 10-12). It is respectfully submitted that such a combination would result in one of the fill time detect electrodes still having a dual use as a measurement electrode, in contravention to Applicants’ claim 12, as amended. It is therefore respectfully submitted that Applicants’ claim 12 is allowable over the references of record.

Claims 13-15 depend from claim 12 and therefore include all of the limitations of claim 12. It is therefore respectfully submitted that claims 13-15 are allowable over the references of record for at least the same reasons set forth above with respect to claim 12.

Claim 16 depends from claim 12 and therefore includes all of the limitations of claim 12. The addition of the Beatty reference does nothing to cure the deficiencies of the Neel and Feldman combination. It is therefore respectfully submitted that claim 16 is allowable over the references of record for at least the same reasons set forth above with respect to claim 12.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance, and respectfully request such action. Applicants respectfully request that the Examiner telephone the undersigned attorney for Applicants at 317-634-3456 if the Examiner does not find that all claims are in condition for allowance as presented herein.

Respectfully submitted,

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